K060719

# VERTE-STACK® Spinal System
# 510(k) Summary
# March 2006

APR 14 2006

I. **Company:** **Medtronic Sofamor Danek**
**1800 Pyramid Place**
**Memphis, TN 38132**
**(901) 396-3133**

**Contact:** **Edward S. Chin**
**Group Director Regulatory and Clinical Affairs**

II. **Proprietary Trade Name: VERTE-STACK® Spinal System**

III. **Classification Name/Product Code: Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060)**

IV. **Product Code: MQP**

V. **Product Description**

The VERTE-STACK® device is a stackable spacer, which inserts between vertebral bodies in the anterior thoracic and lumbar spine. The device is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine. The construct is not intended to be employed as a stand-alone device. The VERTE-STACK® device is fabricated and manufactured from POLYETHERETHERKETONE (PEEK OPTIMA LT1) along with either titanium or tantalum markers. Alternatively the entire device may be manufactured from titanium alloy.

The design of the VERTE-STACK® device includes a variety of stackable components of different sizes and heights. The stackable components are designed to suit the individual patient pathology.

The VERTE-STACK® device may be used individually, or two or more may be stacked together in order to accommodate the individual anatomical requirements of the vertebral space created by the corpectomy.

The VERTE-STACK® Spinal System must be used with additional anterior and/or posterior spinal instrumentation to augment stability. VERTE-STACK® constructs manufactured with PEEK may be used with stainless steel or titanium supplemental fixation devices. Titanium VERTE-STACK® constructs may not be used with stainless steel supplemental fixation devices.

The purpose of this submission is to include slightly modified components to the previously cleared VERTE-STACK® Spinal System.

## VI. Indications

The VERTE-STACK® Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK® Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK® device is to be used with the Medtronic Sofamor Danek ZPLATE II Anterior Fixation System, the DYNALOK™ CLASSIC Spinal System, the VANTAGE™ Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON® Spinal System, the GDLH® Spinal System and/or their successors. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

## VII. Substantial Equivalence

Documentation was provided which demonstrated that the subject VERTE-STACK® Spinal System components are substantially equivalent to components previously cleared in VERTE-STACK® Spinal System 510(k) applications K041556, (SE07/01/04), K043561, (SE 12/27/04), K052931, (SE 11/16/05) and K030736 (SE 04/02/03).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2006

Medtronic Sofamor Danek
c/o Mr. Edward S. Chin
Group Director, Clinical and Regulatory Affairs
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K060719
Trade/Device Name: VERTE-STACK™ Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: March 16, 2006
Received: March 17, 2006

Dear Mr. Chin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

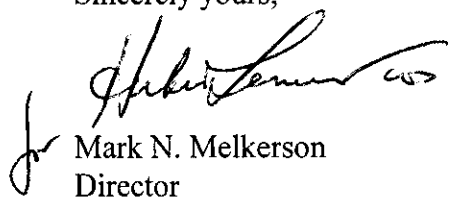
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K060719

Device Name: VERTE-STACK® Spinal System

**Indications for Use:**

The VERTE-STACK® Spinal System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The VERTE-STACK® Spinal System is to be used with supplemental fixation. Specifically, the VERTE-STACK® device is to be used with the Medtronic Sofamor Danek ZPLATE II Anterior Fixation System, DYNALOK™ CLASSIC Spinal System, the VANTAGE™ Anterior Fixation System, TSRH® Spinal System, CD HORIZON® Spinal System, the GDLH® Spinal System, or their successors. Additionally, the VERTE-STACK® device is intended to be used with bone graft.

Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K060719